REMARKS

The following issues were raised by the Examiner:

A. Restriction Requirement and Withdrawal of Claims 16-37
B. Drawings
C. Sequence Compliance
D. Status of Application
E. 35 USC 112, second paragraph
F. 35 USC 112, first paragraph
G. 35 USC 102
H. 35 USC 103
I. Provisional Double Patenting

Each of these issues is addressed below in turn.

A. Restriction and Withdrawal of Claims 16-37.

Applicants note with appreciation the Examiner's modification of the restriction requirement. Without agreeing with the restriction (but to further the prosecution), Claims 1 and 9 have been limited to the APC gene in accordance with the Examiner's re-joining of groups I, VI, XI, XVI and XXI. The Examiner, however, has withdrawn Claims 16-37 on the grounds that "there being no allowable generic or linking claim." (Office Action, p.2). Applicants, on the other hand, have linked Claim 16 to Claim 2, and Claims 24-29 to Claim 16. It is believed that this provides ample grounds to permit the continued prosecution of Claims 1-2, 4-6, 9, 11-13, 16 and 24-29. Claims 30-37 have been withdrawn.

B. Drawings

The Examiner has made certain observations concerning the drawings. First, it should be stressed that the formal drawings did not introduce changes (indeed, the original figures were quite good, with the exception of the gels, which were Xerox copies when submitted initially). Second, Figures 15 and 17 were, indeed, submitted with figure numbers. However, a review on the PAIR system reveals that the scanning department at the PTO cut off the bottom of these pages. Obviously, this is a PTO problem. Nonetheless, if the Examiner needs the paper originals for any reason, these can be supplied.

C. Sequence Compliance

The Examiner argues that the submission of the sequencing listing is non-compliant. However, page 8 of the September 7, 2004 submission notes: "Applicants assert that no new matter is introduced through the instant Preliminary Amendment or any of the attached documents or media."

D. Status of Application

The Examiner points out that the parent application has issued. Accordingly, Applicants have amended the specification to reflect this change.

E. 35 USC 112, second paragraph

The Examiner argues that the term "epitope marker" is vague. Applicants disagree. The meaning of claim terms is determined, in part, by a reading of the specification – and the specification makes clear the meaning of this term. Nonetheless, Claims 1 and 9 have been amended to specify a discrete group of epitope tags, rendering the rejection moot. The amendment was made to further the prosecution, and Applicants hereby expressly reserve the right to pursue the original claims, similar claims, or broader claims in future prosecution.

F. 35 USC 112, first paragraph

The Examiner argues that the claims do not satisfy the written description requirement in that the primers are allegedly only "defined by their function." First, even if this were true (which it is not), the PTO issued the Mullis PCR patents in the 1980s with claims directed to ANY primer sequence that would hybridize to ANY template. The priority date for the present patent application is 1999 – fifteen years later! Certainly, one skilled in the art understands the principles of primer complementarity to target sequences at this point. Second, the primers – as claimed – specify structural features (ribosome binding sites, start and stop codons, etc.) that are VERY well known to those skilled in the art. That is to say, the term "stop codon" (for example) invokes a very limited number of well-known sequences (which the Examiner must acknowledge, given he is a Ph.D.). While the term promoter does encompass a larger number of

sequences, such sequences are well-characterized and published in both academic papers and patents. Without waiving this argument, but to further the prosecution, and hereby expressly reserving the right to prosecute the original claims (or similar claims), Applicants have amended Claims 1 and 9 to specify the T7 promoter.

G. 35 USC 102

The Examiner acknowledges that the Rowan reference cannot anticipate without the Examiner's unique interpretation of "epitope marker." Given the above-mentioned amendments (done because of the restriction requirement), this issue is moot.

H. 35 USC 103

The Examiner argues that one skilled in the art would combine the teachings of Suzuki et al. with the teachings of the Rowan reference. There is no basis for this argument. Suzuki et al. teach a yeast cloning approach which is distinct from the protein truncation test of Rowan which involves cell free translation (as does present claim 24, above). Thus, at the very outset, the rejection is not supported because the assays are significantly different. Moreover, the Examiner is utilizing a discussion section of Suzuki et al. which describes what Suzuki has not yet done (in the context of the yeast cloning approach). Finally, as perhaps most importantly, Suzuki et al. appear to be discussing a future "simplified" assay where ONLY a C-terminal marker is employed ("simply by testing whether the yeast transformants express a carboxy-terminal marker peptide or not"). This teaches away from a two marker system.

CONCLUSION

The Applicant believes that the arguments and amendments set forth above traverse the Examiner's rejections and therefore, request that all grounds for rejection be withdrawn for the reasons above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect at 617.984.0616.

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By: _____

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